

**AXIS® Fixation System**  
**510(k) Summary – K062254**

**JUN 16 2008**

**June 2008**

- I. Company:** Medtronic Sofamor Danek USA  
1800 Pyramid Place  
Memphis, Tennessee 38132  
Telephone: (901) 396-3133
- Contact:** Lee Grant  
Sr. Regulatory Affairs Specialist
- II. Proposed Proprietary Trade Name:** AXIS® Fixation System
- III. Classification Name(s):** Spinal Interlaminar Fixation Orthosis; Single/Multiple Component Metallic Bone Fixation Appliances and Accessories; Pedicle Screw Spinal System; Class: II, III (for degenerative disc disease) and/or unclassified; Product Code(s): KWP, HRS, MNI, NKB, NKG; and Regulation No.: 888.3050, 888.3030, and/or 888.3070
- IV. Description:** The AXIS® Fixation System consists of a variety of shapes and sizes of bone plates, screws, and associated instruments. Fixation is provided by bone screws inserted into the lateral masses of the cervical spine using a posterior approach.
- The AXIS® Fixation System implant components are made of titanium alloy. Titanium alloy and stainless steel implants should not be used together in a spinal construct. The AXIS® Fixation System components are supplied non-sterile.
- V. Indications for Use:** The AXIS® Fixation System may be used from the C2 to T3 (inclusive) spinal levels for the following indications: (1) trauma, including spinal fractures and/or dislocations; (2) cervical instability or deformity; (3) pseudarthrosis or failed previous fusions; and (4) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies; and/or degenerative disc disease of the facets with instability. Spinal screw fixation is to be achieved with posterior pedicle and/or lateral mass screws and plates implanted from C2 to T3 levels inclusively. Supplemental posterior fixation with the ATLAS™ Cable must be used. Refer to the ATLAS® Cable System package insert and surgical technique for further instructions. Additionally, the AXIS® Fixation System must be used with autograft or allograft.
- VI. Substantial Equivalence:** The AXIS® Fixation System is substantially equivalent to other commercially available posterior cervical fixation systems and other pre-enactment devices including the TOWNLEY® Transfacetpedicular Fixation System (K953076, SE 2/19/97 and K021705, SE 07/24/02). Literature, mechanical test reports and clinical data were supplied in support of establishing a claim of substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Medtronic Sofamor Danek  
% Mr. Lee Grant  
Senior Project Specialist, Regulatory Affairs  
1800 Pyramid Place  
Memphis, Tennessee 38132

JUN 16 2008

Re: K062254  
Trade/Device Name: AXIS<sup>®</sup> Fixation System  
Regulation Number: 21 CFR 888.3070  
Regulation Name: Pedicle screw spinal system.  
Regulatory Class: III  
Product Code: NKB, NKG, MNI, HRS, KWP  
Dated: March 14 2008  
Received: March 18, 2008

Dear Mr. Grant:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Lee Grant

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**510(k) Number (if known):** K062254

**Device Name:** AXIS® Fixation System

**Indications for Use:** The AXIS® Fixation System may be used from the C2 to T3 (inclusive) spinal levels for the following indications: (1) trauma, including spinal fractures and/or dislocations; (2) cervical instability or deformity; (3) pseudarthrosis or failed previous fusions; and (4) degenerative disc disease (DDD) as defined by neck and/or back pain of discogenic origin as confirmed by radiographic studies; and/or degenerative disc disease of the facets with instability. Spinal screw fixation is to be achieved with posterior pedicle and/or lateral mass screws and plates implanted from C2 to T3 levels inclusively. Supplemental posterior fixation with the ATLAS™ Cable must be used. The AXIS® Fixation System must be used with autograft or allograft.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

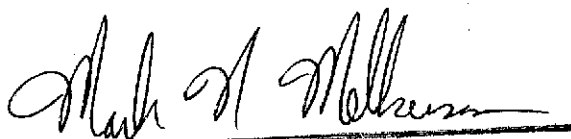
AND/OR

Over-The-Counter Use             
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



**(Division Sign-Off)**

**Division of General, Restorative,  
and Neurological Devices**

**510(k) Number**           K062254          

page 1 of 1